MAY - 1 2001

K002742

510(k) Summary

SphygmoCor™ SCOR-Mx

Common/Classification Name: Blood Pressure Computer as classified under 21 CFR 870.1110

PWV Medical Pty Ltd.
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Contact: Ross Harricks, Director

Prepared: August 24, 2000

A. Legally Marketed Predicate Devices

The SphygmoCor SCOR-Mx is substantially equivalent to a standard intravascular pressure catheter attached to a conventional manometer [such as Transpac (Abbott Critical Care, Chicago North) and the 8 French 100 cm long Cordis tip manometer catheter (catalog No. 811-170) , the Millar Mikro-Tip® - One Pressure Sensor - SPC-320 and the Millar Mikro-Tip® - Two Pressure Sensor - SPC-721] and Hewlett Packard Blood Pressure Monitor. Both types of systems have the same intended use, which is to provide the calibrated central aortic pressure waveform.

B. Device Description

The SphygmoCor SCOR-Mx is a computerized tool for the assessment of blood pressure. The SphygmoCor can estimate the calibrated ascending aortic pressure waveform using the pressure waveform recorded in the radial artery. The system is designed for use with a conventional invasive radial artery blood pressure monitor in the hospital setting.

The radial pressure signal is recorded by the standard blood pressure monitor with an invasive radial artery pressure transducer. The radial artery pressure signal produced by the monitor is then continuously processed in the SphygmoCor electronics module to produce the estimated ascending aortic pressure waveform. Periodically, waveform data are captured for analysis and calculation of central pressure parameters.

The signal processing electronics module is attached to a PC computer through a serial RS-232C port.

The PC computer continuously displays the measured (radial) and estimated (ascending aortic) waveforms. An IBM-compatible computer (notebook or desktop) is used to run the the SphygmoCor computer software suite.

C. Indications for Use

The SphygmoCor Mx is indicated for use in those patients where information related to the ascending aortic pressure is desired, but in the opinion of the physician, the risks of the cardiac catheterization procedure may outweigh the benefits.

D. Substantial Equivalence Summary

The primary function of both types of devices is to provide the calibrated ascending aortic blood pressure waveform. The intravascular pressure catheter blood pressure monitor requires the catheter to be placed directly in the aorta to acquire the ascending aortic pressure measurement. The SphygmoCor Mx uses the available radial artery signal from a blood pressure monitor. It derives from this radial waveform the calibrated estimate of the ascending aortic blood pressure waveform and a range of central arterial indices of ventricular-vascular interaction.

A study was carried out which compares the waveforms measured invasively with a catheter in the aorta with the waveform produced by the SphygmoCor Mx. This study demonstrated that the calibrated estimate of ascendingl aortic blood pressure waveform derived by the SphygmoCor Mx is substantially equivalent to the waveform recorded with the intravascular catheter.

E. Technological Characteristics

See Device Description, above.

F. Testing

The entire system has been tested to demonstrate compliance with IEC-601-1 (including its subparagraphs) Electro-Medical Equipment Safety Standard. Testing was done to demonstrate compliance with this standard for input voltages of both 110 and 220 volts. The biocompatibility testing clause of the standard was not applied since there are no patient contacting materials. This testing demonstrates that the SphygmoCor Mx meets electrical and environmental safety standards for safe use.

Software for the SphygmoCor Mx was carefully developed and tested to ensure safe and reliable function of the system. The documentation is provided which describes the information specified in the FDA document, Reviewer Guidance for 510(k)

Submissions of Computer Controlled Medical Devices. Since the device provides information to a practitioner which is only adjunctive to the available radial pressure signal and is not the sole basis for diagnosis, the level of concern for the software is low.

The software has been extensively tested and validated. A bibliography which identifies publications describing the validation work is provided in the 510(k) submission. Data from a recent clinical trial is also provided which demonstrates that the recorded calibrated aortic pressure waveform is equivalent to the calibrated ascending aortic pressure waveform derived from the radial signal. The various indices calculated from each waveform are also shown to be equivalent.

G. Conclusions

PWV Medical has demonstrated through its comparison of performance with the predicate device that the SphygmoCor Mx (Model SCOR-Mx) is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2001

PWV Medical Pty Ltd.
c/o Ms. Kirsten H. Paulson
Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville MD 20852

Re: K002742
Trade Name: SphygmoCor™ Mx Aortic Blood Pressure Analysis System
Regulatory Class: II (two)
Product Code: DSK
Dated: January 29, 2001
Received: January 31, 2001

Dear Ms. Paulson:

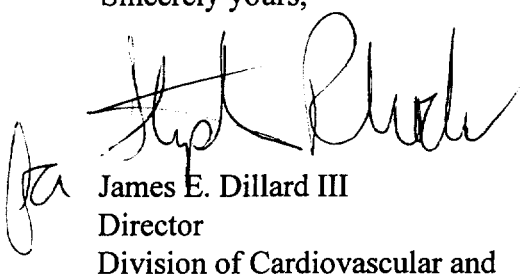
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002742

Device Name: SphygmoCor™ Blood Pressure Analysis System (SCOR-Mx)

Indications for Use:

The SphygmoCor™ SCOR-Mx provides an estimated, calibrated ascending aortic blood pressure waveform and a range of central arterial indices. The SphygmoCor, used with a calibrated radial artery waveform measured with a pressure transducer in the radial artery is indicated for use in the hospital setting. It is to be used in those patients where information related to the ascending aortic pressure is desired, but in the opinion of the physician, the risks of the cardiac catheterization procedure may outweigh the benefits.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002742